भारतीय मानक
Indian Standard

IS 17787 : 2021

चिकित्सीय वस्त्रादि — बिना बुने हुए वाइप्स — विशिष्टि

Medical Textiles — Nonwoven Wipes — Specification

ICS 59.080.30

© BIS 2021

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली – 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

December 2021 **Price Group 3**

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

The composition of the Committee responsible for the formulation of this standard is given in Annex C.

For the purpose of deciding whether a particular requirement of this standard iscomplied withthe final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — NONWOVEN WIPES — SPECIFICATION

1 SCOPE

1.1 This standard specifies minimum performance requirements for single use nonwoven dry or wet wipes used for baby care and personal hygiene (baby, adult, facial, skin etc). This standard does not cover wet wipes impregnated/coated with alcohol and other wipes with germicidal claim (numerical germ kill, disinfection etc.).

1.2 This standard does not cover the requirement of chemical, cleaning agent, moisturizing agents, fragrance, preservative etc. impregnated/coated on the product. The different types of chemicals/ingredients used for these products shall be in the permissible limit defined by FDA (Food and Drugs Authority of India) or other regularity authority for the purpose.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following term shall apply:

3.1 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.

3.2 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

3.3 Non-woven — Nonwovens are structures of textile materials, such as fibres, continuous filaments, or chopped yarns of any nature or origin, that have been formed into webs by any means, and bonded together by chemical, mechanical, heat or solvent treatment etc., excluding the interlacing of yarns as in woven fabric, knitted fabric, laces, braided fabric or tufted fabric.

3.4 Single-use Product — Product intended by the manufacturer to be used only once.

4 MATERIAL

The non-woven fabric used for manufacture of wipes shall confirm to IS 17788 : 2021.

5 WORKMANSHIP AND FINISH

The wipes shall be clean and free from substances liable to cause tendering during storage. The length and width of the wipes shall be as per the agreement between buyer and seller.

6 REQUIREMENTS

6.1 The wipes shall conform to the requirements specified in Table 1.

6.2 Good Manufacturing Practice Guideline for Hygiene Requirement

The wipes shall be manufactured under good hygienic conditions. The general guidelines for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex B.

6.3 Seal Leakage Test

Take 10 packets of wipes randomly. Put the packet in the chamber of suitable leakage test apparatus and ensure that the water level is up to the lid of the stand. Start the vacuum pump and maintain the vacuum in chamber up to 3.0 inch Hg (75 mm Hg). If pressure is increased to more than 3.0 inch Hg (75 mm Hg), slightly close the valve and maintain 3.0 inch Hg (75 mm Hg) pressure in vacuum chamber for 30 s.

During the vacuum position observe the packet. If no repetitive air bubbles are generated in 30 s, the packet is leak proof. Repeat the same procedure for remaining packets, all packets shall be leak proof.

7 PACKING

The wipes shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be, such as to maintain the integrity of the product throughout its shelf life.

Table 1 Performance Requirement for Nonwoven Wipes

(*Clause* 6.1)

Sl No. (1)	Characteristics (2)	Requirement (3)	Method of Test, Ref To (4)
i)	Length and width, mm	As agreed to between the buyer and the seller with a tolerance of ± 1 mm	-
ii)	*p*H	4.5 – 7.5	IS 1390
iii)	Total viable count, (*cfu/g*), *Max*	100	IS 14648
iv)	Pseudomonas aeruginosa	Not detectable per gm	IS 14648
v)	Staphylococcus aureus	Not detectable per gm	IS 14648
vi)	Candida albicans	Not detectable per gm	IS 14648
vii)	E. coli	Not detectable per gm	IS 14648
viii)	Anti-bacterial activity (*optional*), absorption method,	≥ 2	IS/ISO 20743

8 MARKING

8.1 Each packet of the wipes shall be legibly and indelibly marked with following information:

a) Name of the product;
b) Length and width of the wipe;
c) Number of wipes in a packet;
d) Manufacturer's name, initials or trademark, if any;
e) Month and year of manufacture, batch/lot number;
f) Intended use for example, baby, adult, facial, skin;
g) Country of origin;
h) Ingredient/chemicals used;
i) Instruction for use, storage and safe disposal;
j) Disposability instructions - The manufacturer shall provide the instruction to users for safe disposal of the product;
k) Shelf life;
l) Anti-bacterial if claimed; and
m) Any other requirement as per *Medical Device Rules,* 2017 or as required by the law in force or as agreed between the buyer and the seller.

8.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

9 SAMPLING AND CRITERIA FOR CONFORMITY

9.1 Lot

All the packets of the same material and dimensions produced under similar conditions of manufacture shall constitute a lot.

9.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

9.1.2 Unless and otherwise agreed, the number of packets to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 2.

9.1.3 These packets shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

9.2 Number of Tests and Criteria for Conformity

9.2.1 All the packets selected as per column 3 of Table 2 shall be examined for workmanship and finish (*see* **5**).

9.2.1.1 Any packet failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

9.2.2 Out of the sample already found satisfactory according to **9.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

9.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective products found in the sample (as per **9.2.2**) is less than, or equal to the acceptance number as given in column 6 of Table 2.

Table 2 Number of Packets to be Selected

(*Clause* 9.1.2, 9.2.1, 9.2.1.1, 9.2.2 *and* 9.2.3)

Sl No.	**Lot Size**	**Non-Destructive Testing**		**Destructive Testing**	
		No. of Packets to be Selected	Acceptance Number	No. of Packets to be Selected	Acceptance Number
	N	n	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13[1]	1	8	0
ii)	281 to 500	20	2	8	0
iii)	501 to 1200	32	3	13	0
iv)	1201 to 3200	50	5	13	0
v)	3201 and above	80	7	20	1

[1] or lot size when less than 13.

ANNEX A

(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
17788 : 2021	Medical textiles — Nonwoven fabric for wipes — Specification
1390 : 2019/ ISO 3071 : 2005	Textiles — Determination of *p*H of aqueous extract (*second revision*)
4905 : 2015/ ISO 24153 : 2009	Random sampling and randomization procedures (*first revision*)
14648 : 2011	Microbiological examination of cosmetics and cosmetic raw materials — Methods of test (*second revision*)
IS/ISO 20743 : 2013	Textiles — Determination of antibacterial activity of textile products

ANNEX B

(*Clause* 6.2)

B-1 GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumers use. Following are recommended guidelines for ensuring hygiene at facilities:

a) Location shall be free from objectionable odours, smoke, dust and other contaminants.
b) Separate areas shall be demarcated for storing raw materials, production and final product storage.
c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
d) Toilet and hand-washing station shall be positioned away from storage/production area.
e) Provision of 70 percent isopropyl alcohol (IPA) solution or equivalent or soap for hand sanitization inside the production facility.
f) Appropriate lighting and proper ventilation of the facility shall be ensured.
g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
h) Regular pest control measures shall be put in place.
j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.
k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. shall be displayed.
m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.
n) Hand hygiene shall be practised during manufacturing.
p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/disinfection of the equipment.

ANNEX C

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

Organization	*Representative(s)*
The South India Textile Research Association, Coimbatore	Dr Prakash Vasudevan (***Chairman***)
3 M India Limited, New Delhi	Shri Kulveen Singh Bali Shrimati Prabha Hegde (*Alternate*)
Association of Indian Medical Devices (AiMeD), New Delhi	Dr G. D. Agarwal Shri Jitendra Sachchade (*Alternate*)
All Indian Institute of Medical Sciences, New Delhi	Dr Vijaydeep Siddharth Dr Anoop Daga (*Alternate*)
Business Coordination House, New Delhi	Shri Sameer Gupta Shrimati Ritika Gupta (*Alternate*)
Cologenesis Healthcare Pvt Ltd, Salem	Shri R. Krishnakumar Shri K. Ramprasad (*Alternate*)
Defence Research and Development Establishment (DRDE), Gwalior	Dr Vikas B. Thakre Shri Suraj Bharati (*Alternate*)
DGAFMS, Ministry of Defence, New Delhi	Col Ramesh Chandra Surg Lt Cdr Kotian V. Gopal (*Alternate*)
DGQA (Ministry of Defence), New Delhi	Shri Senthil Kumar Shri Arnab Das (*Alternate*)
Director General of Health Services, New Delhi	Dr Inder Prakash Dr Sunny Swarnkar (*Alternate*)
M/s Dispoline India Private Limited, Bengaluru	Shri Sumit Marwah.
Dr Sabharwals Manufacturing Labs Pvt Ltd, Panchkula	Shri Manish Sabharwal Shri Dhruv Sabharwal (*Alternate*)
Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr Sanjiiv Rehlan Ms Tulsi (*Alternate*)
Ginni Filaments Limited, Noida	Shri Pramod Sharma
Govt Medical College and ESI Hospital, Coimbatore	Dr N. Tamilselven Dr K. Kulendaivelu (*Alternate*)
Indian Council of Medical Research, New Delhi	Dr Chandra Shekhar
Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal Prof Vipin Kumar (*Alternate*)
Indian Technical Textile Association, Mumbai	Dr Anup Rakshit Mr Mahesh Kudar (*Alternate*)
Johnson and Johnson Ltd, Mumbai	Shri Ram Shukla Mr Vivek Bansal (*Alternate*)
Kamal Healthcare Pvt Limited, Tamilnadu	Shri S. Sankar Marimuthu
KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade Shri S. Kumar Subramanian (*Alternate*)
Livinguard Technologies Pvt Ltd, Mumbai	Ms Shivani Swami Dr Shefali Mishra (*Alternate*)

Organization	*Representative(s)*
Maulana Azad Medical College, New Delhi	Dr P. N. Agarwal Dr U. C. Verma (*Alternate*)
Medline Healthcare Industries Pvt Ltd, Pune	Mr Anthony Dcosta Shri Dhaval Ghuge (*Alternate*)
National Physical Laboratory, New Delhi	Dr Sanjay Yadav Dr Shankar G. Aggarwal (*Alternate*)
Nobel Hygiene, Mumbai	Shri Kamal Johari Mr Joy Devassy (*Alternate*)
Office of the Drug Controller (CDSCO), Delhi	Dr Ravikant Sharma Mr Arvind Hiwale (*Alternate*)
Office of the Textile Commissioner, Mumbai	Shri Sivakumar S. Shri Narrotam Kumar (*Alternate*)
PGIMER, Chandigarh	Dr Pankaj Arora
Procter and Gamble Co, Mumbai	Shri Prashant Jadhav Shri Sivakumar (*Alternate*)
Surgicotfab Textile Pvt Ltd, Ahmedabad	Shri Paresh Patel
Textiles Committee, Mumbai	Shri Kartikeyan Dhanda Ms Shilpi Chauhan (*Alternate*)
The Bombay Textile Research Association, Mumbai	Shrimati Aruna Apte
The South India Textile Research Association, Coimbatore	Dr E. Santhini Shri Veera Subramaniam (*Alternate*)
The Synthetics and Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur Shrimati S. S. Dongre (*Alternate*)
Vimta Lab Limited, Hyderabad	Dr Mukesh Agrawal Shri Jagadeesh Kodali (*Alternate*)
BIS Directorate General	Shri A. K. Bera, Scientist 'F' and Head (TXD) [Representing Director General (*Ex-officio*)]

Member Secretary

Shri Dharmbeer
Scientist 'C' (TXD), BIS

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: TXD 36 (16335).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:

		Telephones
Central	: Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	2323 7617 2323 3841
Eastern	: 1/14 C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi KOLKATA 700054	2337 8499, 2337 8561 2337 8626, 2337 9120
Northern	: Plot No. 4-A, Sector 27-B, Madhya Marg CHANDIGARH 160019	265 0206 265 0290
Southern	: C.I.T. Campus, IV Cross Road, CHENNAI 600113	2254 1216, 2254 1442 2254 2519, 2254 2315
Western	: Manakalaya, E9 MIDC, Marol, Andheri (East) MUMBAI 400093	2832 9295, 2832 7858 2832 7891, 2832 7892

Branches : AHMEDABAD. BENGALURU. BHOPAL. BHUBANESHWAR. COIMBATORE. DEHRADUN. DURGAPUR. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. JAMMU. JAMSHEDPUR. KOCHI. LUCKNOW. NAGPUR. PARWANOO. PATNA. PUNE. RAIPUR. RAJKOT. VISAKHAPATNAM.

Published by BIS, New Delhi